

10/13/04



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,089	12/29/2003	Andrei W. Konradi	42837-20010.21	6848

7590 09/13/2004

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EXAMINER

PATEL, SUDHAKER B

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/748,089	KONRADI ET AL.
	Examiner	Art Unit
	Sudhaker B. Patel, D.Sc.Tech.	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 February 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 2-74 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/17/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

Applicants' communication papers dated 12/29/03 and 2/17/04 are acknowledged. Applicants have cancelled claims 2-74. Claim 1 is a generic claim related to a method for treating a disease mediated by VLA-4 by compounds of generic Formulae Ia & Ib. Therefore the claim in this application is claim1 only.

Upon further review and consideration, this application is not ready for allowance in as is state for the reasons stated bellow.

***Specification***

1. The disclosure is objected to because of the following informalities: It does not state exactly that the instant application is a CON of U.S. Application Sr. No. 10251442, filed September 20, 2002, now allowed, which is a DIV of U.S. Application Sr. # 09489377, filed 1/22/99, now U.S.P.6492372, which claims benefit of U. S. Application Sr. No. 60160999, filed 10/21/1999..

Appropriate correction is required.

***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6492372. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use for the compounds is overlapping with the instantly claimed invention.

4. The instant application differs from the ref.' 372 by reciting broader scope of use for the compounds recited in generic Formulae Ia and Ib. See ref. '372 claim 6 in column 146, lines 53-65.

This will extend the monopoly of the ref.' 372.

5. Claim 1 is also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-74 of the copending U.S. Application Sr. No. 10251442, filed 9/20/02, now allowed. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use for the compounds is overlapping with the instantly claimed invention.

The instant application differs from the ref.' 442 by reciting broader scope of use for the compounds recited in generic Formulae Ia and Ib.

This will extend the monopoly of the ref.' 372 & '442.

#### **6. *Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 related to a method of use, does not exactly and definitely state a single ans specific disease mediated by the VLA-4.

9. Claim 1 recites a method of treatment of a generic disease mediated by VLA-4 by administering a pharmaceutical composition comprising a [pharmaceutically acceptable carrier and a therapeutically effective amount of a compound of generic Formulae Ia & Ib.

10. The claim remains silent in defining the exact procedure or step of administration. This will additionally raise the issues related to enablement under 35 U.S.C. 112 paragraph one.

11. Claim1 recites a method of treating a disease mediated by VLA-4 by the pharmaceutical composition of compound(s) of generic Formulae Ia & Ib, and also enantiomers, diastereomers and pharmaceutically acceptable salts thereof. Replacement of "and" by "or" is required.

12. Claim1 recites at the end: " .... Has a binding affinity to VLA-4 as expressed by an IC50 of about 15uM or less". The terms "about and or less" are not exact and definite. Does it include zero?

13. This recitation will additionally raise the enablement issues related to 35 U.S.C. 112 paragraph one, because such analytical method as recited will serve the preliminary purpose of screening the compounds, and not for exactly treating any and all diseases mediated by VLA-4.

14. 14 Claim 1 related to method for treating a disease does not exactly and definitely recite to whom the treatment is to be give.

***Information Disclosure Statement***

15. The information disclosure statement (IDS) submitted on 2/17/ is being considered by the examiner. Signed copy of the same is enclosed for applicants' record.

***Conclusion***

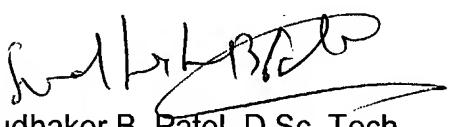
16 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671.

The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James Wilson at (571) 272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sudhaker B. Patel, D.Sc. Tech.  
July 26, 2004



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